UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re: RESTASIS (CYCLOSPORINE OPHTHALMIC EMULSION) ANTITRUST LITIGATION	Case No. 18-MD-2819 (NG) (LB)
This Document Relates To: All End Payor Plaintiff Class Actions	Oral Argument Requested

ALLERGAN, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE TESTIMONY OF DR. JONCA BULL AND DR. FRÉDÉRIC LALLEMAND

FILED UNDER SEAL PURSUANT TO THE STIPULATED CONFIDENTIALITY ORDER (ECF NO. 68)

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Abbreviation	Meaning
Allergan MSJ	Allergan's September 22, 2020 Motion for Summary Judgment
Allergan MSJ Ex.	Exhibit to Allergan's September 22, 2020 Motion for Summary Judgment
Allergan SMF	Statement of Material Facts submitted in support of Allergan's September 22, 2020 Motion for Summary Judgment
EPPs	End-Payor Plaintiffs
Mem.	Memorandum of Law in Support of End-Payor Plaintiffs' Motion to Exclude Testimony of Dr. Jonca Bull and Dr. Frédéric Lallemand
Mem. Ex.	Exhibit to the Memorandum of Law in Support of End-Payor Plaintiffs' Motion to Exclude Testimony of Dr. Jonca Bull and Dr. Frédéric Lallemand

INTRODUCTION

EPPs do not challenge that Drs. Jonca Bull, M.D. and Frédéric Lallemand, Ph.D. are experts in the fields on which they opine—nor would there be any basis to do so, given Dr. Bull's experience working at the FDA on Restasis and bioequivalence issues, and Dr. Lallemand's experience inventing and manufacturing cyclosporine ophthalmic emulsions. Instead, EPPs attempt only to pick off certain opinions that they consider irrelevant, unreliable, or otherwise legally precluded. In doing so, EPPs misinterpret the applicable legal standards and often the experts' opinions as well. EPPs' criticisms either go entirely to the weight of the challenged opinions (not their admissibility) or are otherwise unsupported in law.

EPPs object to broad swaths of Dr. Lallemand's report relating to his opinions that Restasis is a unique formulation with unexpected properties compared to prior art formulations, and his rebuttal of EPPs' experts' opinions regarding Allergan's presentation and declarations to the Patent Office. Mem. at 5-9. EPPs contend that collateral estoppel precludes Dr. Lallemand from offering these opinions because Allergan lost on the issue of obviousness in the Restasis patent litigation. But EPPs fail to meet their burden to show that the issues presented in the prior patent litigation are identical to Dr. Lallemand's challenged opinions. The opinions instead relate to the never-before-litigated claims that EPPs assert in this separate antitrust litigation—namely, EPPs' claim that Allergan committed fraud in obtaining patents on Restasis and that Allergan's infringement suits to enforce those patents were a sham.

EPPs also object that particular opinions are unreliable because they lack sufficient support. But an expert's opinion is only subject to exclusion under *Daubert* for lack of support if it "is so fundamentally unsupported that it can offer no assistance to the jury." *Hollman v. Taser Int'l Inc.*, 928 F. Supp. 2d 657, 670 (E.D.N.Y. 2013). Each of the challenged opinions is more than adequately supported, as explained below in Section II. This Court should not grant EPPs'

implicit request to cross beyond its "gatekeeping" function and evaluate the weight of the experts' opinions, which the Supreme Court has recognized is the province of the factfinder. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596-97 (1993).

EPPs additionally contend that two of Dr. Lallemand's opinions about deficiencies in the Restasis draft guidance's in vitro option are irrelevant. EPPs overlook that arguments undermining the scientific validity of the in vitro option make it more probable that Allergan's citizen petitions had scientific merit and thus a chance of success, which is sufficient to immunize the petitions from liability according to the *Noerr-Pennington* doctrine. *See* Allergan MSJ § II.A (citing *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-63 (1993) ("*PRE*")). And although EPPs object to Dr. Bull's reliance on and agreement with certain of Dr. Lallemand's opinions, it is proper for one expert to rely on another where, as here, both experts are qualified to render the opinions and subject to cross-examination on them.

Because none of the grounds to exclude have merit, the Court should deny the motion.

BACKGROUND

I. Dr. Bull

Dr. Jonca Bull, M.D., is a board-certified ophthalmologist who practiced ophthalmology full-time for more than a decade, treating thousands of patients for dry eye conditions, before going to work for the FDA in the division covering ophthalmic products and, later, in the Office of the FDA Commissioner. Bull Rpt. ¶¶ 8-10.[1] While at the FDA, Dr. Bull became familiar with Restasis because she oversaw and worked with the team that reviewed, and ultimately approved, Allergan's new drug application for Restasis. *Id.* ¶ 16. At the FDA, Dr. Bull also gained experience working on generic bioequivalence issues and responding to citizen petitions.

[1] The Bull and Lallemand expert reports are included in the joint appendix of expert reports.

From 2000 to 2005, while an Office Director and Acting Division Director within the Office of New Drugs, Dr. Bull assisted attorneys in the Office of Regulatory Policy with responding to citizen petitions, effectively serving as a consultant. *Id.* ¶ 19. She also "reviewed and edited responses to citizen petitions." *Id.* Also from 2000 to 2005, Dr. Bull attended "regular meetings with the Office of Generic Drugs concerning bioequivalence issues, including with topical products such as dermatologic products." *Id.* ¶ 20. During this period, the FDA recognized Dr. Bull with the Leadership Excellence Award. *Id.* ¶ 26. She returned to work in the FDA's Office of the Commissioner from 2012 to 2017. *Id.* ¶¶ 13, 23. In 2017, she received an award from Women in Ophthalmology for her work in the field of ophthalmology. *Id.* ¶ 26. This is her first time providing expert testimony in a litigation.

II. Dr. Lallemand

Dr. Frédéric Lallemand, Ph.D., has studied and developed cyclosporine ophthalmic products for approximately 20 years. His thesis to obtain his Ph.D. in Pharmaceutical Sciences in 2004 concerned how "to design water-soluble prodrugs of cyclosporine A and to optimize their properties for ocular delivery." Lallemand Rpt. ¶ 6. Dr. Lallemand then joined a pharmaceutical company where he developed a new type of cyclosporine ophthalmic emulsion used to treat dry eye disease: Ikervis (cyclosporine ophthalmic emulsion, 0.1%). *Id.* ¶ 9. Dr. Lallemand is the "named inventor of all of the patents covering Ikervis." *Id.* ¶ 10. He worked for 10 years developing it, including developing its manufacturing process. *Id.* Ikervis achieved approval for sale by the European Medicines Agency in 2015. *Id.* ¶ 9. Currently Dr. Lallemand is a pharmaceutical development consultant. *Id.* ¶¶ 16-17.

LEGAL STANDARD

Expert testimony is relevant if it "has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would

be without the evidence." *In re Restasis Antitrust Litig.*, 2020 WL 2280144, at *1 (E.D.N.Y. May 5, 2020) (citations omitted). Expert testimony is sufficiently reliable if: "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *Restasis*, 2020 WL 2280144, at *2.

ARGUMENT

I. Dr. Lallemand's Challenged Opinions Are Not Subject to Collateral Estoppel

EPPs seek to exclude over one hundred pages of Dr. Lallemand's report—233 paragraphs in total—on the basis that Allergan is collaterally estopped from offering his opinions. Mem. at 5-9. But collateral estoppel only applies to *identical* issues actually litigated and decided in a prior proceeding, and it is EPPs' burden to prove that Dr. Lallemand's challenged opinions are identical to the issues in the Restasis patent litigation. EPPs do not come close. Moreover, even if EPPs had met their burden (they did not), fairness precludes the result EPPs seek here.

A. EPPs Have Not Met Their Burden to Prove the Issues Addressed by Dr. Lallemand and Those Faced by the District Court Are Identical

"The party seeking to invoke issue preclusion has the burden of proving that 'the identical issue was raised in a previous proceeding.'" *Bader v. Goldman Sachs Grp., Inc.*, 455 F. App'x 8, 9 (2d Cir. 2011). EPPs fail to meet their burden in the first instance because they provide no analysis whatsoever to show that the 233 paragraphs of Dr. Lallemand's report they seek to exclude express opinions on issues identical to those decided in the Restasis patent litigation. In fact, EPPs cite *only two paragraphs* of Dr. Lallemand's report in their conclusory section on "identical issues," Mem. at 6, and even for those two paragraphs fail to show that the substance of the opinions is identical to issues decided in the patent litigation.

The paragraphs EPPs cite (¶¶ 96 and 289) address issues different from the ones EPPs

argue were decided in the patent litigation. The issues EPPs identify as previously litigated are whether "*the patents were valid* because Restasis exhibited unexpected results," and specifically whether the prior art "teaches away from increasing the castor oil concentration" because irritation and decreased efficacy were expected. Mem. at 6 (emphasis added). But Dr. Lallemand does not opine that the Restasis patents are valid, in the cited paragraphs or anywhere.

EPPs have no analysis whatsoever for the other 231 paragraphs they seek to exclude, and therefore do nothing to carry their burden to show that the opinions expressed in these paragraphs are identical to issues decided in the Restasis patent litigation. Moreover, a review of the challenged sections shows that they provide highly detailed and wide-ranging scientific facts supportive of the reasonableness of Allergan's patent positions and the statements of its declarants—not simply opinions on the validity issues (unexpected results and teaching away) that EPPs argue were decided in the Restasis patent litigation. Lallemand Rpt. ¶¶ 92-324.

EPPs also fail to meet their burden because in order for issues to be identical, the legal standards in the two cases cannot be "significantly different." *Computer Assocs. Int'l, Inc. v. Altai, Inc*., 126 F.3d 365, 371 (2d Cir. 1997); *see also, e.g.*, *In re OxyContin Antitrust Litig*., 994 F. Supp. 2d 367, 412 (S.D.N.Y. 2014). Here, however, the legal standards governing the district court's decision in the patent litigation are meaningfully different from those in this case.

The prior proceeding was a patent litigation in which one of the legal questions at issue was whether the patent claims were invalid for obviousness. *Allergan, Inc. v. Teva Pharm. USA, Inc*., 2017 WL 4803941, at *17 (E.D. Tex. Oct. 16, 2017). All of the district court's analyses and findings regarding unexpected results and teaching away were made in view of the standards necessary to accept or reject a legal conclusion of obviousness.

In the current proceeding, the issue is not whether the Restasis patents are actually valid,

or whether the facts show unexpected results or teaching away sufficiently to support non-obviousness, but whether Allergan's arguments to the PTO regarding unexpected results and teaching away were *fraudulent*. The inquiries here include whether Allergan made its arguments with an intent to deceive, whether Allergan acted with anticompetitive intent, and whether its positions were so unreasonable that arguing non-obviousness was a sham. *See Ritz Camera & Image, LLC v. SanDisk Corp*., 700 F.3d 503, 506 (Fed. Cir. 2012); *Nobelpharma AB v. Implant Innovations, Inc*., 141 F.3d 1059, 1068-71 (Fed. Cir. 1998); *PRE*, 508 U.S. at 60-61.

Dr. Lallemand's testimony supports Allergan's defense that the positions it took before the PTO were positions a reasonable scientist could believe to be true. Neither Dr. Lallemand nor Allergan is taking the position in the current litigation that the patents at issue are valid, and EPPs do not point to any evidence to the contrary. The different legal standards therefore establish that the issues in the patent litigation and the opinions challenged here are not identical.

That "unexpected results" and "teaching away" are factual questions underpinning the legal question of obviousness does not compel a different conclusion. It is true that in some cases where "the issue to which the plaintiff seeks to give preclusive effect concerns 'only the existence or non-existence of certain facts,' and not 'the legal significance of those facts' . . . the 'legal standards to be applied' need not be identical." *Bifolck v. Philip Morris USA Inc.*, 936 F.3d 74, 81 (2d Cir. 2019). Here, however, the fact issues to which EPPs seek to give preclusive effect were inextricably bound with the "legal significance of those facts" in an altogether different legal context—namely, an obviousness inquiry.

For example, the court in the patent litigation made clear that its decision addressed whether the results Allergan identified were "unexpected" in the specific way required to defeat obviousness—not whether Allergan's declarants had a good faith basis for their arguments. The

court repeatedly relied on the legal standard that, "[t]o be probative of nonobviousness, unexpected results must be 'different in kind and not merely in degree from the results of the prior art.'" *Allergan*, 2017 WL 4803941, at *19, *46. Even if Allergan's declarants did not show results "different in kind" to defeat obviousness, that does not mean that they did not show results that were unexpected to a "degree" that would suggest a lack of fraudulent intent.[2]

Because EPPs failed to meet their burden to prove the issues in the prior proceeding were identical to those in Dr. Lallemand's challenged opinions, collateral estoppel does not apply.

B. Collateral Estoppel Cannot, in Fairness, Preclude Dr. Lallemand from Providing Testimony Directly Responsive to EPPs' Experts

EPPs cannot exclude Dr. Lallemand's testimony on unexpected results or teaching away for the additional reason that fairness dictates that Allergan be permitted to respond to the issues EPPs themselves first raised. "Even if a court concludes that all four prongs of the nonmutual offensive collateral estoppel analysis have been established, it must still assure itself that it is fair to apply the doctrine." *Bifolck*, 936 F.3d at 84.

Applying collateral estoppel to exclude Dr. Lallemand's challenged opinions would be unfair in this case because the challenged sections respond directly to issues first raised in the reports of EPPs' experts Dr. Hanes and Dr. Calman. Dr. Calman's opening report opined at length that Restasis's formulation did not show unexpected results. *See* Calman Rpt. ¶¶ 24, 374. Dr. Hanes's opening report similarly presented a lengthy opinion that the patent claims were obvious and walked through the evidence presented by Allergan to the PTO, opining on whether it demonstrated unexpected results in order to support the allegation that Allergan knew that its

[2] Indeed, although the court held the patents invalid as obvious post-trial, it also denied the generics' pre-trial motion to add inequitable conduct claims, expressly ruling that the claims would be unlikely to succeed. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 2017 WL 119633, at *6 (E.D. Tex., Jan. 12, 2017).

patent claims were obvious. *See* Hanes Rpt. § V.A. Both experts even attached their invalidity reports from the patent litigation to their expert reports here.

Without opining that the Restasis patents are actually valid, Dr. Lallemand offers his rebuttal opinions evidencing the reasonableness of Allergan's arguments to the Patent Office, and fairness demands that he be able to present this directly responsive testimony to the jury. Indeed, the only case EPPs have cited that addresses the preclusive effect of a patent case in an antitrust litigation holds that a defendant can present expert evidence regarding the strength of its rejected patent positions—including "evidence aimed at convincing the jury that [defendants'] positions were reasonable, such as explanation of the arguments made and opinions presented during" the patent litigation. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2015 WL 6750899, at *9 n.9 (E.D. Pa. Nov. 5, 2015) (emphasis omitted); *see also id.* at *6-7. That is so even though opinions that the patents are "currently valid" are precluded. *Id.*

Moreover, the court's reasoning in *King Drug* goes directly to the issue of fairness:

> Throughout the course of this litigation, Plaintiffs have continually indicated that they intend to introduce evidence regarding the weakness of the RE '516 patent in the antitrust trial. Plaintiffs have asserted that this evidence is relevant to establish Defendants' knowledge that the RE '516 patent was invalid, procured by fraud, and not infringed, and thus, to help establish that Defendants had anticompetitive motivations in entering into the settlement agreements. However, at the same time, Plaintiffs seek to preclude Defendants from responding to this evidence.
>
> Plaintiffs' position is inconsistent. . . . I conclude that if Plaintiffs pursue a theory that a weak patent is probative of antitrust motivations in settling the Paragraph IV litigation, I will allow Defendants to respond and attempt to rebut this evidence.

Id. *6. EPPs' position here is equally inconsistent and unfair, yet EPPs ignore these concerns.

EPPs' perfunctory "fairness" analysis addresses only four non-exclusive factors identified in a 1979 decision and ignores their own more recent authority identifying some of the very circumstances present here as critical to the fairness inquiry. Mem. at 7. As the Second

Circuit recently explained, one of the factors a court may consider is "whether [the two cases] involve different causes of action." *Bifolck*, 936 F.3d at 84. Here, the different causes of action in the patent and antitrust litigations implicate totally different legal standards. In fairness, the district court's decision in the patent case that Allergan's evidence of unexpected results was not sufficient to defeat obviousness should not preclude Allergan from presenting evidence in this case aimed at showing that its positions before the Patent Office were reasonable.

II. None of EPPs' Attacks on Reliability Are Grounds for Excluding the Opinions

A. Dr. Bull's Opinions About the Types of Arguments That Persuade the FDA to Grant a Citizen Petition Are Supported

As part of EPPs' effort to show that Allergan had no chance to succeed on its citizen petitions, and thus fall within *Noerr-Pennington*'s sham exception, EPPs move to exclude certain of Dr. Bull's opinions regarding types of petitioner arguments that have a reasonable chance to persuade the FDA to change the bioequivalence standard in draft guidance. Mem. at 9-10.

The opinions EPPs challenge are subsidiary to Dr. Bull's broader opinions that (i) a "reasonable scientific argument" can persuade the FDA to revise draft bioequivalence guidance, (ii) a "scientific argument about bioequivalence standards can be reasonable without including data that proves FDA's standards are insufficient," and (iii) the "FDA has changed bioequivalence standards absent proof that a drug satisfying such requirements was not bioequivalent." Bull Rpt. ¶¶ 130-33. EPPs do not challenge these opinions, which are amply supported not only by Dr. Bull's extensive FDA experience, but also by her discussion of four exemplary citizen petitions that the FDA granted even though petitioners did not provide proof that a drug could satisfy existing guidance and yet still not be bioequivalent. Bull Rpt. ¶¶ 135-40. EPPs do not deny that Dr. Bull can offer these opinions and supporting evidence.

Instead, EPPs move to exclude just two subsidiary opinions about specific types of petitioner arguments that can persuade the FDA: those based on "a hypothetical but theoretically sound concern" about the guidance and those based on "an ongoing debate inside FDA about an issue that does not appear to be fully resolved." Mem. at 1, 9-10. EPPs contend there is insufficient support that these two types of arguments can persuade the FDA. *Id.* That is wrong.

1. Dr. Bull's Opinion That a "Hypothetical But Theoretically Sound Concern" Can Persuade the FDA Is Supported

As an initial matter, EPPs' disagreement that an argument based on "a hypothetical but theoretically sound concern" can persuade the FDA seems to be effectively a quibble about word choice rather than substance. As noted, EPPs do not challenge Dr. Bull's opinions that a citizen petition can be successful even without proof that a drug satisfying the challenged guidance was not bioequivalent, where the petition is based on another "reasonable scientific argument," such as one "based on the scientific literature . . . or identifying a missing parameter that needs to be evaluated in order to truly demonstrate bioequivalence." Mem. at 9-10 (quoting Bull Rpt. ¶¶ 130-31). And EPPs do not dispute that the four citizen petitions Dr. Bull discusses are evidence of those opinions. *Id.* But the same evidence supports the challenged opinion. A "hypothetical but theoretically sound concern" is simply one that has a sound scientific basis, although not proven by data. That label appropriately describes the four citizen petitions Dr. Bull discusses because, in each case, the FDA granted the petition even though petitioners did not provide proof that a drug could satisfy the existing guidance yet still not be bioequivalent.

Amrix. There is no dispute that this citizen petition asked the FDA to change the draft guidance to require an in vivo bioequivalence test comparing the generic to Amrix when both were sprinkled on applesauce. Mem. at 11-12. Nor is there any dispute that the petition was granted, even though it did not prove that a generic version of Amrix could satisfy the existing

guidance yet fail bioequivalence on the missing applesauce test. Bull Rpt. ¶ 135. Instead, as EPPs concede, the petition rested on a different scientific basis: it raised the *hypothetical* concern that "the formulation of a generic [Amrix] product *may differ* in material respects from the Amrix formulation," in ways that would be reflected in the applesauce test. Allergan MSJ Ex. 168 at 7-10. And it showed that the concern was theoretically sound because general FDA guidance recommended a sprinkle test for generics if the branded drug's label allowed administration by sprinkling (as Amrix's did). *Id.*

Kadian. EPPs concede that this citizen petition asked the FDA to add two in vivo bioequivalence tests to its existing guidance, namely for the 10-mg-strength and 200-mg-strength capsules, because those two capsules used a pellet formulation different from the strengths required to be tested under the draft guidance. Mem. at 12; Bull Rpt. ¶ 136. EPPs argue that the petition does not support Dr. Bull's opinion that a hypothetical concern has a chance to persuade the FDA because the FDA's response said it was granting the request "[b]ased on an analysis of the formulations of each strength and the in vivo bioequivalence studies conducted between the strengths of the reference product." Mem. at 12. That statement does not undermine Dr. Bull's opinion, however, because it does not state or imply that the petitioner provided proof that the capsules using the different pellet formulation failed bioequivalence.

To the contrary, the Kadian citizen petition was successful after doing nothing more than (i) pointing out that the 10-mg and 200-mg strengths had different pellet formulations than the strengths tested under the existing draft guidance, and (ii) presenting the *hypothetical* that a different pellet formulation "*potentially compromises* the reliability of the bioequivalence data that an ANDA applicant would obtain." Allergan MSJ Ex. 169 at 15 (emphasis added).

Nitrolingual Pumpspray. EPPs agree with Dr. Bull that the FDA granted this citizen

petition's request to measure an additional substance in the in vivo testing—TNG itself, rather than just metabolites of TNG—and that the information the citizen petition provided to support its argument was publicly available scientific articles concerning differences between TNG and metabolites of TNG. Mem. at 12-13; Bull Rpt. ¶ 137. EPPs imply that the cited articles demonstrate that the concern raised by the petition was not hypothetical, but that is wrong.

As Dr. Bull explains, the concern that measuring the metabolites of TNG alone was insufficient to ensure bioequivalence raised in the petition was hypothetical. *See* Mem. Ex. 9 at 8 (FDA Resp. to Nitrolingual Pumpspray Citizen Petition). None of the cited articles proved that a product that was bioequivalent according to the metabolites could nonetheless fail bioequivalence when TNG was measured. *See* Ex. A at 790-91 (Santoro, *Plasma Levels of Glyceryl Trinitrate* (2000)); *see also* Ex. B (Jensen, *Plasma Concentrations of Glyceryl Trinitrate* (2004)) (no mention of bioequivalence); Ex. C (Needleman, *Relationship Between Glutathione-Dependent Dinitration* (1969)) (same). Nevertheless, the FDA granted the petition without any mention of information other than what the citizen petition provided. Mem. Ex. 9 at 8 & nn.23-25. This citizen petition therefore succeeded in persuading the FDA to change a bioequivalence guidance by raising a hypothetical, although theoretically sound, concern.

Lanoxin. EPPs concede that the FDA granted this citizen petition requesting to change the Lanoxin guidance to require a "four-way, fully replicated crossover design" for its in vivo tests, rather than the "two-way crossover in vivo studies" required by the draft guidance. Mem. at 13. Moreover, they do not dispute that the petition provided no proof that a drug could satisfy the existing guidance yet fail bioequivalence in the four-way, fully replicated test. *Id.* Instead, as EPPs concede, the petition merely argued that Lanoxin is a narrow therapeutic index drug, and pointed out that *other* guidance recommended four-way, fully replicated crossover designs for

testing *other* narrow therapeutic index drugs. *Id.* The concern that there was any issue with Lanoxin was hypothetical, but theoretically sound, and persuaded the FDA. Bull Rpt. ¶ 138.

EPPs also contend that other evidence of record contradicts Dr. Bull's opinion, citing an email from Allergan consultant Robert Pollock, testimony from former Allergan employee Damon Burrows, and the opinion of EPPs' expert, Dr. Kessler. Mem. at 10-11. None of the cited evidence is actually contradictory, and all of it is addressed by Dr. Bull. Bull Rpt. ¶¶ 132-33 & n.133. But to the extent EPPs' evidence shows any "weakness in the factual basis" of Dr. Bull's opinion, it "bears on the weight of the evidence, not its admissibility." *U.S. Bank Nat'l Ass'n v. PHL Variable Life Ins. Co.*, 112 F. Supp. 3d 122, 134 (S.D.N.Y. 2015); *see also Clark v. Travelers Cos.*, 2020 WL 473616, at *5 (E.D.N.Y. Jan. 29, 2020) (denying motion to exclude allegedly self-contradictory expert testimony).

Pollock email. EPPs cite Allergan consultant Robert Pollock's email that "[i]n *mostly* all of the FDA petition approvals," there is an issue that is "clinically relevant" and "supported by data and that data must rise to the level of clinical significance." Mem. Ex. 3 (emphasis added). Pollock added that "failed petitions *typically* cite back to the lack of clinical relevance." *Id.* (emphasis added). Pollock's email is inadmissible hearsay. He is not a witness nor expert in this case. Regardless, Dr. Bull explained that Pollock's email was "consistent with my opinion that data is useful, but not necessary, to include in a citizen petition to have a reasonable chance of success." Bull Rpt. ¶133 n.133. EPPs also fail to mention that Pollock supported Allergan's citizen petition arguments, calling them "strong." *See* Ex. D at 423 (KS-RESANT-00000415).

Burrows testimony and Kessler opinion. EPPs cite deposition testimony by Allergan former employee Damon Burrows that "the likelihood of there being a successful or unsuccessful petition was highly dependent upon data as opposed to argument," and that

petitions "without data have a very high failure rate." Mem. Ex. 4 at 57:17-23. EPPs also cite a statement from the report of their retained expert, Dr. Kessler, that "'a drug company is likely to move the Agency to grant its requested actions if it provides clinically significant or clinically meaningful data or information supportive of the requests made.'" Mem. at 11 (quoting Kessler Rpt. ¶ 81). Both statements are about what arguments are *most likely* to persuade the FDA, which is different from Dr. Bull's opinion about what arguments have a *reasonable chance* of persuading the FDA (or "some chance," which is all the law requires). Dr. Bull explained that such comments were "consistent with [her] opinion that data is useful, but not necessary, to include in a citizen petition to have a reasonable chance of success." Bull Rpt. ¶ 133 n.133.[3]

Because EPPs' evidence goes to, at most, the weight of the evidence rather than its admissibility, EPPs have not identified any valid ground to exclude the opinions in question.

2. Dr. Bull's Opinion That an Argument Based on an "Ongoing Debate Inside FDA" Can Persuade the FDA Is Supported

Dr. Bull's opinion that a petition can persuade the FDA by making an argument based on "an ongoing debate inside FDA about an issue that does not appear to be fully resolved" is also amply supported, both by Dr. Bull's experience at the FDA and the granted Lanoxin petition.

Dr. Bull's FDA experience includes participating in decision-making on "challenging policy issues" where there was debate, Bull Rpt. ¶ 202, and thus she is qualified to testify that "the existence of a vigorous scientific debate generally suggest that both sides hold reasonable opinions, not that one side is making frivolous points," *id.* ¶ 214. That experience shows that when a debate within the FDA remains unresolved, that generally means each side has scientifically valid points, and an argument based on either side's points can persuade the FDA.

[3] Dr. Kessler's opinion about what type of information can persuade the FDA is also subject to a pending motion to exclude, including for lack of appropriate qualifications. Allergan Mem. in Support of Mot. to Exclude Dr. Christians and Dr. Kessler at 16-19 (Sept. 29, 2020).

The Lanoxin citizen petition also proves the chance of success in making a request on an unresolved issue. There, the FDA had convened an advisory committee of outside experts to recommend the proper type of bioequivalence test for a particular category of drugs that included Lanoxin. Ex. E at 12 (Lanoxin citizen petition). The fact that the FDA convened an advisory committee is evidence the issue was unresolved within the FDA, and thus that there were competing views within the FDA. *See* Bull Rpt. ¶¶ 463-67 (describing the reasons the FDA convenes advisory committees). The Lanoxin citizen petition made a request on an issue that an advisory committee had considered and that the FDA had not yet resolved with respect to Lanoxin—*i.e.*, to require a more-thorough bioequivalence test, Ex. E at 15-17—and the FDA granted that request, Mem. Ex. 10 at 16. This granted request supports Dr. Bull's opinion.

The evidence EPPs cite in their brief is not to the contrary because none of it addresses the circumstances of an unresolved, ongoing debate within the FDA. *See* Mem. at 13. EPPs concede that the FDA granted the Lanoxin request "[b]ased on the Advisory Committee's recommendation and related published scientific literature," *id.*, but overlook that the reason an advisory committee is convened is that the FDA considers an issue unresolved. In any event, at most EPPs' criticisms go to the weight of the opinion and are not grounds for exclusion.

B. Dr. Lallemand's and Dr. Bull's Opinions That Cyclosporine Is in the Aqueous Phase Are Supported

EPPs overstate and misrepresent the opinions of Drs. Lallemand and Bull regarding the role of the aqueous phase of the Restasis emulsion in an attempt to paint those opinions as out of step with the evidence. In fact, the opinions are supported by appropriate evidence. Although EPPs may disagree with Dr. Lallemand's and Dr. Bull's conclusions, the issue is a straightforward dispute between experts, and thus unfit for a motion to exclude. *See, e.g., In re Blech Sec. Litig.*, 2003 WL 1610775, at *25 (S.D.N.Y. Mar. 26, 2003) ("appropriate safeguards"

are vigorous cross-examination and the presentation of contrary evidence, rather than exclusion).

EPPs' characterizations of Dr. Lallemand's and Dr. Bull's opinions on this matter are inconsistent and inaccurate. The header in this section of their Memorandum alleges that the Defendants' experts opine that "*clinically relevant* amounts of cyclosporine in Restasis are found in the aqueous phase or micelles." Mem. at 14 (emphasis added). EPPs later write of Drs. Lallemand and Bull that "[t]hey further suggest that appreciable amounts of cyclosporine are within the micelles rather than solubilized in the oil globules, and this is *clinically significant*." *Id*. (citing Lallemand Rpt. ¶¶ 85-87; Bull Rpt. ¶¶ 74-77) (emphasis added).

In fact, the experts offer no such opinions, and none of the cited paragraphs from their reports say anything about "appreciable" or "clinically significant" amounts. Lallemand Rpt. ¶¶ 85-87; Bull Rpt. ¶¶ 74-77. Moreover, all experts in the case agree that cyclosporine is present in the aqueous phase but "only a very low concentration." Lallemand Rpt. ¶ 85; *see also* Bull Rpt. ¶ 73; Hanes Rebuttal Rpt. ¶ 299. The dispute between the parties' experts is therefore a question of degree, and whether that "very low concentration" in the aqueous phase should be considered and measured. Drs. Bull and Lallemand opine that the amount of cyclosporine in all phases should be determined, consistent with the FDA's recognition that the distribution of cyclosporine in ***all*** the phases of the emulsion (and not just the oil phase) is a critical physicochemical attribute that must be addressed by generics seeking to prove bioequivalence. *See, e.g.*, Allergan MSJ Ex. 115 (Oct. 2016 Draft Guidance).

EPPs' assertion that [redacted] is contradicted by EPPs' own statements [redacted] Mem. at 15 (emphasis added). EPPs generally make carefully qualified statements regarding the amount of cyclosporine expected in the aqueous phase. *Id.* at

14-16, 21 [redacted] *Id.* at 15. Thus, the opinions EPPs seek to exclude are actually supported by the very evidence EPPs cite. EPPs citations to case law concerning opinions "based on facts that are indisputably wrong" is therefore unavailing. *Id.* at 21.

Drs. Lallemand and Bull also opine that emulsions are complex, and that the degree of cyclosporine in the aqueous phase of an emulsion will depend on the particular excipients and manufacturing processes used. Lallemand Rpt. ¶¶ 71-87 (citing reviews of ophthalmic emulsions); Bull Rpt. ¶¶ 73-80 (citing, among other sources, the Lallemand report). They further explain that cyclosporine present in the aqueous phase "would have a greater affinity with tissues such as the cornea or conjunctiva." Bull Rpt. ¶ 77. These opinions are based upon reliable evidence, as explained below, and should not be excluded simply because EPPs' experts disagree. *See In re Joint S. & E. Dist. Asbestos Litig.*, 52 F.3d 1124, 1135 (2d Cir. 1995) ("[C]ourts should not arrogate the jury's role in evaluating the evidence and the credibility of expert witnesses by simply cho[o]s[ing] sides in [the] battle of the experts." (citation omitted)).

As an initial matter, Drs. Lallemand and Bull explain their own expertise and the basic concepts of chemistry upon which their opinions rely, including the concepts of solubility, hydrophobic/hydrophilic relationships, and the behavior of surfactants like Polysorbate 80. *See, e.g.*, *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 413 (S.D.N.Y. 2016) ("[E]xpert testimony may be based on 'experience alone—or experience in conjunction with other knowledge, skill, training or education.'"). Each expert devotes multiple paragraphs to explaining the chemistry of emulsion systems, both generally and in regards to cyclosporine

emulsions specifically. *See, e.g.*, Lallemand Rpt. ¶¶ 69-87. These principles of chemistry provide a "traceable, analytical basis in objective fact" that meets the standard of Rule 702. *Blech*, 2003 WL 1610775, at *25. EPPs simply ignore these analyses.

Both experts also cited external support. For example, Dr. Lallemand relies on both his own (vast) experience with cyclosporine-based drugs and the teachings and classifications of Winsor for his opinion that the size, shape, and extent of micelles in a particular cyclosporine emulsion can vary, which then "may influence the efficacy profile of an ophthalmic emulsion." Lallemand Rpt. ¶¶ 81-95. For his opinion that "CsA may be absorbed more rapidly and in a greater amount when present in the aqueous phase and the surfactant interface than CsA present in oil globules," *id.* ¶¶ 84-86, 575-76, Dr. Lallemand relies on his expertise, a published study, and Allergan's centrifugation study. *See id.* ¶ 86 n.36 (citing Gore article) *id.* ¶¶ 575-77 (centrifugation study); Mem. Ex. 27 (summarizing research). EPPs' only objection to this evidence is that it was authored by Allergan scientists. That goes to weight, not admissibility.

Drs. Bull's and Lallemand's challenged opinions on micelles are also well supported. Mem. at 20-21. For example, the opinions are supported by a journal article on ophthalmic drug bioequivalence published by an FDA employee who worked on the Restasis draft guidance, which says that applicants should measure and understand the amount of cyclosporine in the aqueous phase, including micelles. Allergan MSJ Ex. 166 at 1037 (Choi article) ("Within an emulsion formulation, the drug may be present in different phases of the formulation (free drug, micelles, globules) in different amounts. . . . The distribution of drug in various phases of the formulation should be comparable between the test and reference products . . . ."). EPPs admit that this is part of the FDA's draft guidance for ophthalmic emulsion, but bizarrely suggest that it does not support Drs. Lallemand and Bull's opinions because it does not report "any data or

studies demonstrating that the cyclosporine in Restasis is present in significant amounts anywhere except the oil globules." Mem. at 20-21.

EPPs' attack is based again upon a misrepresentation of the experts' opinions. They have opined simply that within the Restasis emulsion, cyclosporine may be present in the different phases of the formulation in different amounts, and thus that the distribution across phases should be measured. *See, e.g.*, Lallemand Rpt. ¶¶ 83-86. Their opinions are based on their expert understanding and supported by the direct conclusion of the draft FDA guidance.

In any event, all of EPPs' critiques go to the weight, not admissibility, of the challenged opinions. EPPs are free to offer expert opinions that contradict Drs. Lallemand and Bull, as well as the FDA guidance in Choi, but their disagreement does not form the proper basis for a motion to exclude. *See, e.g.*, *DPWN Holdings (USA), Inc. v. United Air Lines, Inc.*, 2019 WL 1515231, at *4 (E.D.N.Y. Feb. 21, 2019) (holding that a battle of the experts is properly argued to a jury).

C. Dr. Lallemand's and Dr. Bull's Opinions That Restasis Is a Narrow Therapeutic Index Drug Are Supported

Similarly, EPPs' disagreements with Dr. Lallemand's and Dr. Bull's opinions that Restasis is a narrow therapeutic index drug are not a proper basis to exclude that opinion. Dr. Lallemand's opinion is properly based on the Allergan clinical studies and his own experience and expertise with Ikervis, which are the type of reliable bases used for this opinion. *Blech*, 2003 WL 1610775, at *25. And Dr. Bull properly relies on Dr. Lallemand for this opinion. EPPs' argument that the opinions should be excluded because they depend on an allegedly "inappropriate comparison" to oral cyclosporine is wrong. Mem. at 21. In fact, the narrow therapeutic window demonstrated by oral formulations of cyclosporine is only part of the basis for Dr. Lallemand's opinion, as discussed below. And Dr. Lallemand himself states that the oral studies are of limited value in understanding the dose-response in the eye. Lallemand

Rpt. ¶ 217 (responding to Dr. Hanes' citation of a study relating to the use of organ transplants).

In addition to studies on oral cyclosporine, Dr. Lallemand relies on the data in the Stevenson and Sall references as well as Allergan's other clinical studies, which relates to *ophthalmic* use of cyclosporine, not oral use. *Id.* ¶¶ 182, 248-249, 258-259, 262-263. According to Dr. Lallemand, the higher prevalence of adverse effects at high concentrations within the treatment window demonstrate that cyclosporine is a narrow therapeutic index drug. *Id.* EPPs do not suggest that the Stevenson data are unreliable on this issue, nor challenge Dr. Lallemand's qualifications to interpret it. And EPPs may test the sufficiency of the data through the traditional and appropriate means of cross-examination and contrary evidence. *See Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 426 (E.D.N.Y. 2011) ("Rule 702 codifies a liberal admissibility standard and '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'").[4]

III. None of EPPs' Attacks on Relevance Are Grounds for Excluding the Opinions

EPPs attempt to exclude as irrelevant Dr. Lallemand's opinions on two topics relating to the physicochemical properties of cyclosporine ophthalmic emulsions: (i) that different manufacturing processes can result in the emulsions having different physicochemical properties; and (ii) that the in vitro option in the Restasis draft guidance omitted physicochemical properties that are needed to determine bioequivalence. Mem. at 23-24. These two opinions easily meet the relevance standard of Rule 401, which requires only that the testimony tends to "make the

[4] EPPs' motion to exclude focuses on "severe toxicity," but that is not the only issue relevant to the question of whether a drug is a narrow therapeutic index drug. Other adverse effects less serious than serve toxicity, such as those reported in the Stevenson study, should also be included. Lallemand Rpt. ¶ 182. EPPs have not offered any evidence for a definition of narrow therapeutic index that is limited to severe toxicity.

existence of any fact that is of consequence . . . more probable or less probable." Fed. R. Evid. 401. The physicochemical properties of cyclosporine ophthalmic emulsions are consequential in this case because they are important to the scientific validity of the in vitro option.

The FDA recognized that a proposed generic version of Restasis could have the same ingredients as Restasis yet not be bioequivalent unless the physicochemical properties were similar. *See, e.g.*, Allergan MSJ Ex. 12 at 644 (FDA's response to first citizen petition). The FDA also recognized that differences in the manufacturing processes of Restasis and proposed generic versions could cause differences in physicochemical properties. *Id.* Thus, the FDA required generic manufacturers seeking approval via the in vitro option to compare proposed generic versions Restasis to Restasis on certain physicochemical properties, originally "[g]lobule size distribution, viscosity, pH, zeta potential, osmolality, [and] surface tension." *Id.* at 642.

Allergan's citizen petitions argued that measuring physicochemical properties according to the draft guidance's in vitro option was not a scientifically valid way to establish bioequivalence, including because the in vitro option omitted an important physicochemical property (drug distribution within each phase of the emulsion), the physicochemical properties were not defined correctly, and there was no correlation between the properties and the in vivo effect in a patient. Allergan SMF 116-20, 161-66, 221-23.

Dr. Lallemand's two challenged opinions are therefore relevant because, like Allergan's citizen petitions, they criticize the in vitro option's list of physicochemical properties and thus make it more probable that Allergan had a chance of success in persuading the FDA, or a court on appeal, to grant the citizen petition's request. *See* Allergan MSJ at 76-77, 81-83. This is consequential because EPPs must disprove Allergan's chance of success to avoid the *Noerr-Pennington* immunity that applies to citizen petitions by default. *See PRE*, 508 U.S. at 60-63.

A. Dr. Lallemand's Opinion That Different Manufacturing Processes Result in Different Physicochemical Properties Is Highly Relevant

EPPs object that Dr. Lallemand's opinion that different manufacturing processes result in different physicochemical properties is irrelevant to the merits of Allergan's citizen petition because the Restasis draft guidance already required measuring the properties that Dr. Lallemand opines could be affected by manufacturing process. Mem. at 23-24. EPPs cite one physicochemical property that Dr. Lallemand identified, pH, which EPPs are correct was already in the draft guidance. But EPPs overlook *five other* physicochemical properties that Dr. Lallemand identified as important that were *not* in the original 2013 Restasis draft guidance: (1) drug distribution in the emulsion's different phases (Lallemand Rpt. ¶¶ 469, 506); (2) the nature and quality of the excipients (*id.* ¶ 452); (3) rearrangement of surfactants (*id.* ¶¶ 510-511); (4) curvature of droplets (*id.*); and (5) degradation of cyclosporine (*id.* ¶ 474).

Because these five properties were not included in the original draft guidance, Dr. Lallemand's opinion that they are affected by different manufacturing processes indicates a defect in the draft guidance's in vitro option. This is relevant because it "tend[s] to make . . . more probable" that there was merit in Allergan's argument that measuring the physicochemical properties in the draft guidance was not a scientifically valid way to establish bioequivalence. *See* Fed. R. Evid. 401; *Hopkins v. Nat'l R.R. Passenger Corp.*, 2015 WL 13741721, at *12-13 (E.D.N.Y. Aug. 20, 2015) (denying motion to exclude opinion about negligence because that opinion tended to make more probable the litigant's claim of recklessness).

B. Dr. Lallemand's Opinion That the In Vitro Option Was Insufficient to Determine Bioequivalence Is Highly Relevant

EPPs also move to exclude as irrelevant Dr. Lallemand's opinion that the in vitro option described in the Restasis draft guidance "omits other important parameters that would be need to be compared in order to determine bioequivalence." Lallemand Rpt. ¶ 509. EPPs argue that this

opinion is "not related in any way to the merits of Allergan's citizen petitions." Mem. at 24.

EPPs overlook that Dr. Lallemand's opinion supports the requests Allergan made in the citizen petitions, and thus is relevant to Allergan's chance of success with the citizen petitions. To support its request that the FDA refrain from approving an ANDA via the in vitro option, Allergan argued in its petitions that the physicochemical properties listed in the draft guidance were not sufficient to ensure bioequivalence. *See* Allergan SMF 116-20, 161-66, 221-23 (detailing the citizen petitions' arguments). Dr. Lallemand identifies three physicochemical properties, omitted from the draft guidance, which he opines would need to be compared to determine whether a generic Restasis product were bioequivalent. Lallemand Rpt. ¶¶ 510-12.

Because Dr. Lallemand opines that necessary elements are missing from the Restasis draft guidance, his opinion shows that Allergan's argument that the in vitro option is not scientifically valid had scientific merit, making it more probable that the petitions had a chance of success. *See* Allergan MSJ at 76-77, 81-83. Testimony on a "central issue in this case and one not easily resolved by lay persons without expert guidance" is relevant and proper expert testimony. *Ajala v. W.M. Barr & Co.*, 2018 WL 6322147, at *6 (S.D.N.Y. Dec. 4, 2018) (relying on these reasons to deny motion to exclude on grounds of irrelevance).

IV. Dr. Bull's Reliance on and Agreement with Dr. Lallemand's Opinions Is Proper

EPPs object that certain paragraphs in Dr. Bull's report improperly reproduce Dr. Lallemand's opinions. Mem. at 3-5. EPPs' objections are based on allegations that Dr. Bull's opinions in the challenged paragraphs "simply parrot" Dr. Lallemand's opinions and will result in needlessly cumulative testimony. *Id.* at 3. Neither concern is justified. The challenged sections represent Dr. Bull's proper reliance on or agreement with Dr. Lallemand on topics Dr. Bull is unquestionably qualified to opine on. And to the extent there is overlap between the doctors, Allergan agrees not to submit duplicative testimony at trial.

Contrary to EPPs' overblown accusation that Dr. Bull "plagiarizes" Dr. Lallemand, *id.*, the challenged sections represent Dr. Bull's proper reliance on or agreement with Dr. Lallemand. Dr. Bull generally cited to Dr. Lallemand's report as the source for the disputed paragraphs either through footnote citations (*see, e.g.*, Bull Rpt. ¶¶ 579-83 citing to Lallemand Rpt. ¶¶ 523-46; Bull Rpt. ¶ 632 citing to Lallemand Rpt. ¶ 571) or in the text of Dr. Bull's statements (*see, e.g.*, Bull Rpt. ¶ 604 ("I agree with Dr. Lallemand"); *id.* ¶¶ 605, 764 (similar)). Overall, Dr. Bull cited to Dr. Lallemand's report more than 20 times in the challenged sections.[5] Dr. Bull's opinions relying on or agreeing with Dr. Lallemand are entirely permissible.

Under Rule 703, experts are permitted to rely on other experts. *See, e.g.*, *Natixis Fin. Prod. LLC v. Bank of Am., N.A.*, 2016 WL 7165981, at *5 (S.D.N.Y. Dec. 7, 2016) (identifying "modern evidence law's apparent recognition that experts often rely on facts and data supplied by third-parties, including other experts"); *U.S. Bank*, 112 F. Supp. 3d at 131; Wright & Miller, Fed. Prac. & Proc. Evid. § 6274 n.50 (1st ed.) ("[T]he Advisory Committee clearly contemplated that experts can base opinions on the opinions of others."). Indeed, even EPPs' own authorities acknowledge as much. *See, e.g.*, *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 664 (S.D.N.Y. 2007); *Member Servs., Inc. v. Sec. Mut. Life Ins. Co. of New York*, 2010 WL 3907489, at *27 (N.D.N.Y. Sept. 30, 2010).

EPPs' authority is inapt because the cases on which they rely deal with situations in which the relied-upon expert was not subject to cross-examination, or the topics were ones on which the challenged expert was unqualified to opine. Mem. at 3. Neither one is true here.

EPPs have had (and will have at trial) a full and fair opportunity to test Dr. Lallemand's

[5] *See* Bull Rpt. ¶¶ 579-83, 600, 604-06, 608-09, 621, 623-24, 629-30, 641-42, 734, 746, 749, 764, 768, 770.

opinions. Unlike in *Malletier*, for example, where the underlying expert was not produced to testify, 525 F. Supp. 2d at 664-65, EPPs deposed Dr. Lallemand and will have the opportunity to cross-examine him at trial. In addition, EPPs were afforded the opportunity for reply testimony from their own experts. The law appropriately distinguishes between "the rather prejudicial circumstance of experts relying upon, or reciting, the opinions of other experts not subject to cross-examination, and modern evidence law's apparent recognition that experts often rely on facts and data supplied by third-parties, including other experts," as Dr. Bull has done here. *Jung v. Neschis*, 2007 WL 5256966, at *16 (S.D.N.Y. Oct. 23, 2007) (emphases omitted).

There also is no reason to strike Dr. Bull's opinions agreeing with Dr. Lallemand,[6] in light of Dr. Bull's unchallenged qualifications to opine on the topics in question. EPPs' reliance on cases that criticize one expert "parroting" another is misplaced because those cases addressed the different situation where the expert at issue was not qualified to give the challenged opinion. *See* Mem. at 3 (citing *Deutz Corp. v. City Light & Power, Inc.*, 2009 WL 2986415, at *6 (N.D. Ga. Mar. 21, 2009); *Malletier*, 525 F. Supp. 2d at 664). Here, EPPs do not argue that Dr. Bull is unqualified to opine on the subject matter of the challenged paragraphs (the manufacturing and testing of cyclosporine ophthalmic emulsions), or any other topic addressed in her report.

Finally, Allergan will not submit duplicative expert testimony at trial, and if Dr. Bull references any opinion of Dr. Lallemand's, it will be Dr. Lallemand's trial testimony. Accordingly, EPPs' objection that Dr. Bull's testimony would be needlessly cumulative and thus excludable under Rule 403 is also unfounded. Mem. at 3.

CONCLUSION

Allergan respectfully requests that the Court deny EPPs' motion.

[6] *See* Bull Rpt. ¶¶ 579, 583, 604, 623-24, 629-30, 642, 734, 746.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 16, 2020, I served the foregoing document, Allergan, Inc.'s Opposition to Plaintiffs' Motion to Exclude Testimony of Dr. Jonca Bull and Dr. Frédéric Lallemand and the accompanying documents on counsel of record for the End Payor Plaintiffs in accordance with Individual Motion Practices 3.C of the Hon. Nina Gershon.

Dated: November 16, 2020

/s/ Matthew C. Parrott
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